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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/450,969 11/29/99 DOUCETTE-STAMM

L PATH99-09A

HM12/0411

EXAMINER

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GENOME THERAPEUTICS CORPORATION
100 BEAVER ST
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CAMPBELL, E

ART UNIT	PAPER NUMBER
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1656

DATE MAILED:

04/11/01

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Please find below and/or attached an Office communication concerning this application or proceeding.**Commissioner of Patents and Trademarks**

Office Action Summary	Application No.	Applicant(s)
	09/450,969	DOUCETTE-STAMM ET AL.
Examiner	Art Unit	
Eggerton A Campbell	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claims 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 20) <input type="checkbox"/> Other: _____ |

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15 Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a *S. Epidermidis* derived polynucleotide, a recombinant vector, a transformed cell, method for producing said expressed protein, classified in class 536, subclass 23.2, Class 514, subclass 44, and Class 435, subclass 69.1.
- II. Claims 17, drawn to a purified *S. Epidermidis* derived polypeptide, classified in class 530, subclass 350.
- III. Claims 24, 27-31, drawn to a method of detecting a *S. Epidermidis* derived polynucleotide via hybridization, classified in class 435, subclass 6.
- IV. Claim 11-16, 18-23, drawn to a vaccine and methods of treatment, classified in class 514, subclass 2, Class 424, subclass 184.1.
- V. Claims 25-26, drawn to computer based system and a computer readable medium, classified in Class 702, subclass 19.

16. The inventions are distinct, each from the other because of the following reasons:

The inventions Groups I and Group II are patentably distinct in structure and physicochemical properties. The invention of Group I consist of nucleic acids and a method of use whereas the invention of Group II consist of the polypeptides, and. Because nucleic acids are composed of nucleotides whereas proteins are composed of amino acids, the inventions have different structures and physicochemical properties. Nucleic acids can be used in a materially different process than proteins such as probes for detecting mRNA expression which is distinct from the polypeptide production resulting from gene expression. taking the product (DNA

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construct) of Group I for transfecting and culturing said mutated gene construct for expression in a cell which are not linked as to form a single general inventive concept.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as recombinant expression .

The inventions Groups I and Groups (IV,V) are patentably distinct in structure and physicochemical properties. The invention of Group I consist of nucleic acids and a method of use whereas the invention of Group IV consist of the vaccines, and a computer system (Group V). Because nucleic acids are composed of nucleotides whereas proteins are composed of amino acids, the inventions have different structures and physicochemical properties. Nucleic acids can be used in a materially different process than proteins such as probes for detecting mRNA expression which is distinct from the polypeptide production resulting from gene expression.

The inventions of Groups II and (III - IV) are drawn to patentably distinct methods. The invention of Group IV involves methods of immunological method steps while the methods of Group III are drawn to nucleic acid hybridization and computer system (Group V). These methods are each using different parameters, different manipulative steps, different starting

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materials and different reagents. Therefore the inventions of Groups I and II are patentably independent and distinct inventions.

The inventions of Groups III , IV - V are drawn to patentably distinct methods. The invention of Group IV involves methods of immunological method steps while the methods of Group III are drawn to nucleic acid hybridization and computer system (Group V). These methods are each using different parameters, different manipulative steps, different starting materials and different reagents. Therefore the inventions of Groups I and II are patentably independent and distinct inventions.

17. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as

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shown by their different classification and because of their recognized divergent subject matter, election of a single group for examination purposes as indicated is proper.

18. Applicant is advised that the response to this election requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

19. Additionally, no matter which group applicant elects, applicant is required to specify no more than ONE specific nucleotide sequence for examination. This requirement is made under O.G. Notice 1192 O.G. 68 (November 19, 1996), as the examination of more than ten sequences in one application would result in an undue search burden on the PTO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eggerton Campbell whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 4:30 PM (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can normally be reached on Monday-Thursday from 8:00 AM to 4:00 PM (EST) and whose telephone number is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall I. Papers may be submitted Monday-Friday between 8:00 am and 4:45 pm (EST). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-4242.



Eggerton A. Campbell Ph.D.

April 09, 2001

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**EGGERTON A. CAMPBELL
PRIMARY EXAMINER**